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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,984	12/09/2003	Dawn Winsor-Hines	TLN-022	9399

959 7590 10/05/2006

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,984	WINSOR-HINES ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3 are pending and being acted upon.

2. This application appears to be compliant with the Sequence Rules,

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed such as the use of anti-CD4 and anti-CD8 antibodies in the claimed methods.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Also, note that the proper designation for "CD8+ T cells", is "$CD8^+$ T cells"
Applicant should amend the entire disclosure to comport for the standard designation of CD-expressing cells by the ordinary artisan for decades now.

Appropriate corrections are required

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

Applicant has not disclosed how to use anti-CD4 / anti-CD8 antibodies (or "a compound that inhibit $CD8^+$ T cells") to induce tolerance to at least one antigen" therapeutically for the antigens and species encompassed by the claimed methods. There is insufficient information or nexus with respect to the in vivo ability of anti-CD4 / anti-CD8 antibodies (or "a compound that inhibit CD8+ T cells") to accomplish the claimed therapeutic endpoint of immunological tolerance.

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of biopharmaceutical drugs and particularly tolerance induction can be species- and model-dependent, it is not clear that reliance on the limited in vivo experimental models accurately reflects the relative efficacy of the claimed tolerance induction regimens.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment.
See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

While applicant has provided various embodiments of "tolerance" on page 3 of the instant specification in the Detailed Description of the Invention,
The last mentioned embodiment that "tolerance is induced in the absence of a therapeutic level of a general immunosuppressant" is the embodiment generally attributed to tolerance by the skilled artisan.

The Background of the Invention on page 1 of the instant specification is consistent with the art-known experience that despite numerous attempts to induce tolerance;
"At present, rejection can only be prevented by the use of long-term chronic) immunosuppression which carries risks of infection, cancer and drug toxicity."

The skilled artisan would not extrapolate the ability to induce immunological tolerance from the limited observations on one baboon in Example 5 on page 29 of the instant specification to the breadth of targeted antigens including alloantigens encompassed by the claimed invention.

Tolerance is the long-lasting non-reactivity of the immune system to a specific set for antigens, maintained without on-going immunosuppression.

Many different strategies have been developed to achieve transplantation tolerance some have which led to indefinite graft survival in rodents, none of these strategies have yet been applied to human patients in a way that allows reliable withdrawal or exogenous immunosuppression. Auchincloss (Chapter 11 in Transplantation Immunology, Bach and Auchincloss Eds. Wiley-Liss, New York, 1995, pages 211-218, see page 211).

While tolerance inducing strategies that have worked well in rodents, such strategies have been much less successful even when tested in nonhuman primates and other large animals. Also, the Conclusion on page 217 states that Although more than a dozen different techniques to induce tolerance in rodents are now available, the fact remains that none of them has been used successfully in the clinic. Inducing transplantation tolerance in human must therefore be very hard to do. And that reading of this chapter should be wary of simple solution to this complex approaches

Similarly, Ding et al. (Pediatr Transplantation 3: 181-192, 1999) states:
"Despite the fact that it has been relatively easy to induce true tolerance in small experimental animals, translating these studies into larger animals and humans has been much more difficult to achieve. Some of the hurdles that may explain this dilemma are summarized in Table 3. Even if we have the ideal strategy to use in humans, the lack of reliable predictable assays for rejection or tolerance still does not allow us to know if a patient is truly tolerant so that immunosuppressive agents may be withdrawn. Rechallenging a transplant recipient with a second test graft to prove tolerance is not feasible. Therefore, we must define achievement for transplantation tolerance in clinical, immunologic and molecular terms."
See entire document, particularly Clinical Tolerance on page 189, column 1.

Particularly with inducing tolerance in humans and with the breadth of antigens, the ordinary artisan would not recognize the attributes of the tolerant state before immunosuppressive therapy is stopped. At present, the ordinary artisan could only stop treatment and hope that rejection or an immune response would ensue.

While the prior art clearly provides for the immunosuppressive properties of use anti-CD4 / anti-CD8 antibodies (or "a compound that inhibit $CD8^+$ T cells"),
the skilled artisan would not have predict that such immunosuppressives in the absence of additional elements, including additional immunosuppressives, continual immunosuppression as well as exogenous antigen would lead to the induction of immunological tolerance to antigens / foreign antigens, as broadly encompassed by the claimed methods.

For example, the claimed methods encompass inducing tolerance to various antigens, including autoantigens or inducing tolerance in autoimmune diseases,
however no in vivo working examples have been provided to exemplify the ability of inducing tolerance to the breadth of antigens encompassed by the claimed methods.

Although in vitro and animal models validate concepts based on studies of human disease, such studies are limited to the acute as opposed to chronic nature of the disease.

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective tolerance-induction therapies, undue experimentation would be required to practice the claimed therapeutic in vivo methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed in vivo methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for inducing immunological tolerance to the scope of antigens and in the scope of primates, particularly humans, encompassed by the claimed methods.

It is noted that for examination purposes, prior art will applied to the instant methods as it reads on inducing long-term antigen specific unresponsiveness in any primate.

7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is drawn to a "pharmaceutical composition comprising ... "a compound that inhibit $CD8^+$ T cells".

Such "compounds" do not meet the written description provision of 35 USC 112, first paragraph. There is insufficient guidance and direction as to the written description of these "compounds", as broadly encompassed by the claimed invention.

While page 4, paragraph 5, of the instant specification appears to disclose only anti-CD8 antibodies and one non-antibody compound beta-galactoside-binding protein as "compounds that inhibit $CD8^+$ T cells".

The instant application has not provided a sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus of "compounds that inhibit $CD8^+$ T cells", broadly encompassed by the claimed invention.

Given the broad structural and functional differences between "compounds that inhibit $CD8^+$ T cells", including even the limited two exemplary embodiments disclosed on page 4 of the specification as filed and the requirement that the "compound" "induce tolerance to at least one antigen",

there is insufficient written description of the broadly recited "compounds that inhibit $CD8^+$ T cells".

Further, the Court has interpreted 35 U.S.C. §112, first paragraph, to require the patent specification to "describe the claimed invention so that one skilled in the art can recognize what is claimed. Enzo Biochem, Inc. v. Gen-Probe Inc, 63 USPQ2d 1609 and 1618 (Fed. Cir. 2002). In evaluating whether a patentee has fulfilled this requirement, our standard is that the patent's "disclosure must allow one skilled in the art 'to visualize or recognize the identity of' the subject matter purportedly described." Id. (quoting Regents of Univ. of Cal. v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed Cir. 1997)).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

Appllicant has been reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday January 2001.

Therefore, there is insufficient written description for "compounds" other than that disclosed in the specification as filed under the written description provision of 35 USC 112, first paragraph.

Applicant is invited to limit the recitation of "compounds" to those disclosed in the specification as filed or preferably anti-CD8 antibodies, given the known ability of anti-CD8 antibodies to act an immunosuppressive agent in therapeutic regimens in order to obviate this rejection.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. As noted above for examination purposes, prior art will applied to the instant methods as it reads on inducing long-term antigen specific unresponsiveness in any primate.

11. Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated Cobbold et al. (U.S. 6,056,956) (1449; #A1) (see entire document).

Cobbold et al. teach methods of inducing long-term antigen-specific immunological non-responsiveness to various antigens, including foreign antigens and transplantation antigens (e.g. see column 3, paragraphs 5-7) as well as effective amounts and dosages of up to 400 mg (e.g. see column 3, paragraphs 2-4) of anti-CD4 and anti-CD8 antibodies (e.g., see entire document, including Claims). Also, it is noted that the dosages employed with murine experimental animals in the Examples would be consistent with the initial dose of a least 40 mg/kg recited in the claimed methods, when scaled up to a primate / human.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to of inducing long-term antigen-specific immunological non-responsiveness to various antigens, including transplantation antigens with effective amounts of anti-CD4 and anti-CD8 antibodies encompassed by the claimed methods.

12. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobbold et al. (U.S. 6,056,956) (1449; #A1) in view of the known use of administering 40 mg/kg of immunosuppressive antibodies in various therapeutic regimens, including transplantation as taught by Frewin et al. (US 2003/0108518) AND/OR Aruffo et al. (U.S. Patent 6,312,693) AND/OR Bugelski et al. (US 2001/0056066).

As noted above, Cobbold et al. teach methods of inducing long-term antigen-specific immunological non-responsiveness to various antigens, including foreign antigens and transplantation antigens (e.g. see column 3, paragraphs 5-7) as well as effective amounts and dosages of up to 400 mg (e.g. see column 3, paragraphs 2-4) of anti-CD4 and anti-CD8 antibodies (e.g., see entire document, including Claims).

Cobbold et al. differs from the claimed methods by not explicitly teaching "an initial dose of at least 40 mg/kg" per se.

The following references provide further evidence that doses of at least 40 mg/kg of immunosuppressive antibodies were known by the ordinary artisan at the time the invention was made.

Frewin et al. teach tolerance induction methods to various antigens, including transplantation antigens (e.g., see [0034] – [0038]) with effective amounts of an initial dose of at least about 40 mg of immunosuppressive antibodies (e.g. see [0042] – [0054]), including anti-CD4 antibodies (e.g., see entire document).

Aruffo et al. teach that tolerance induction regimens encompass various doses, including 40 mg/kg and 100 mg/kg of immunosuppressive antibodies (see entire document, including Example 3, particularly columns 15-19).

Bugelski et al. teach dosing regimens, including initial doses of at least 40 mg/kg of therapeutic antibodies, including anti-CD4 antibodies (e.g., see Dosing in paragraphs [0036] – [0038]), in methods of treating various inflammatory conditions encompassed by the claimed methods, including transplantation (e.g., see paragraph [0034] – [0035]) (see entire document).

Given the teachings of the prior art of using high doses of immunosuppressive antibodies, including doses of at least 40 mg /kg, in various immunosuppressive / tolerance induction regimens, the ordinary artisan would have been motivated to administer anti-CD4 and anti-CD8 antibodies in such initial high doses to provide a sufficient amount of immunosuppressive antibodies to achieve long-term antigen-specific unresponsiveness as taught by Cobbold et al. as well as Frewin et al., Aruffo et al. and Bugelski et al. One of ordinary skill in the art would have been motivated to test and use high doses of anti-CD4 and anti-CD8 antibodies in order to saturate antigen-binding sites and to induce a tolerance-permissive environment, as acknowledged by the prior art references (e.g. see column 3, paragraphs 3-4 of Cobbold et al.) at the time the invention was made. It appears that the claimed dosing of at least 40 mg/kg and the modes of administration are consistent with the teachings of the prior art's teaching of high doses of immunosuppressive antibodies in regimens to induce a tolerance-permissive environment, including in the context of transplantation antigens and practiced by the ordinary artisan at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending USSN 11/158,505 in view of Cobbold et al. (U.S. 6,056,956) (1449; #A1).

The instant and copending claims are drawn to the similar and obvious methods of inducing tolerance with high doses of anti-CD40 antibodies. The copending claims of USSN 11/158,505 do not recite the use of anti-CD8 antibodies per se. However, as noted above in the prior art rejections, Cobbold et al. teach methods of inducing long-term antigen-specific immunological non-responsiveness to various antigens, including foreign antigens and transplantation antigens (e.g. see column 3, paragraphs 5-7) as well as effective amounts and dosages of up to 400 mg (e.g. see column 3, paragraphs 2-4) of anti-CD4 and anti-CD8 antibodies (e.g., see entire document, including Claims). Also, it is noted that the dosages employed with murine experimental animals in the Examples would be consistent with the initial dose of a least 40 mg/kg recited in the claimed methods, when scaled up to a primate / human. The combination of anti-CD4 and anti-CD8 antibodies to induce long-term antigen-specific unresponsiveness was well known and practiced at the time the invention was made, as taught by Cobbold et al. Therefore, the instant and copending methods are obvious over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

15. Claims 1-3 are directed to an invention not patentably distinct from claims 1-21 of commonly assigned USSN 11/158,505 for the reasons above in Section 14.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSN 11158,505, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 29, 2006